IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Khosravi, Farhad et al.

Serial No.: 09/427,260

Filed: October 25, 1999

For: STRETCHABLE ANTI-BUCKLING COILED-SHEET STENT

Group Art Unit: 3738

Examiner: B. Pellegrino

RULE 132 DECLARATION

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

1. I, Eric Leopold, am the Vice President of Research and Development at NovoStent Corporation of Santa Clara, California. My responsibilities at NovoStent include designing novel stents and stent delivery systems, initially for treatment of Superficial Femoral Artery disease. I hold a Bachelor's Degree in Biomedical Engineering from the University of Iowa, and a Master's Degree in metallurgical and materials engineering from San Jose State University. A copy of my resume is attached as Exhibit 1.

CERTIFICATE OF MAILING
37 CFR §1.8

I hereby certify, pursuant to 37 CFR §1.8, that I have reasonable basis to expect that that this paper or fee (along with any referred to as being attached or enclosed) would be mailed or transmitted on or before the date indicated with the United States Postal Service with sufficient postage as first class mail on the date shown below in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 6/29/05

Valerie Cloyd

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702563-4004 C2F

2. I have no financial interest in Endotex Interventional Systems, Inc. ("Endotex"), which I am advised is the assignee of any patents that may issue from the above-referenced patent Application ("the Application").

3. I know Farhad Khosravi, who I am advised is one of the inventors named on the Application. Mr. Khosravi and I worked together at one time while we both were employed at Guidant Corporation in the early 1990s, and I have maintained professional contact with Mr. Khosravi from time to time since then. I am also a personal friend of Joseph Tartaglia, President of Endotex. I am not personally acquainted with Himanshu Patel, who I am advised is the other inventor named on the Application.

4. I have diligently reviewed a document that has been identified to me as an Office Action mailed on September 29, 2004 in the above-identified Application ("the Office Action"), and the following patents referred to by the Examiner in the Office Action: U.S. Patent No. 5,441,515 to Khosravi et al. ("the Khosravi patent"), U.S. Patent No. 5,800,520 to Fogarty et al. ("the Fogarty patent"), and U.S. Patent No. 5,895,406 to Gray et al. ("the Gray patent"). A copy of the Office Action is attached as Exhibit 2. Copies of the Khosravi patent, the Fogarty patent, and the Gray patent are attached as Exhibits 3 through 5, respectively.

5. The opinions I provide herein are based on my review of the materials listed in Paragraph 4 and my general knowledge of stents and stent manufacturing.

6. In my opinion, one of ordinary skill in the art of stents and stent manufacturing as of October of 1999 would likely possess a bachelor's degree in mechanical or biomedical engineering with areas of study including metals and other materials typically used to construct stents and other medical devices. In addition, one of ordinary skill in the art would typically have an understanding of coronary disease and percutaneous transluminal coronary angioplasty procedures.

7. As indicated in Paragraph 4, I diligently reviewed the Khosravi, Fogarty, and Gray patents. Based on the review of those patents and my general knowledge in the area of stent and stent manufacturing, I do not believe that those patents or the general knowledge of one of ordinary skill in the art provide any suggestion or motivation to combine the teachings of those patents in the manner that the Examiner suggests on pages 2 and 3 of the Office Action.

8. I have arrived at these conclusions based in part, but not limited to, the reasons provided below.

9. The Fogarty patent describes intraluminal prostheses, particularly stents, that comprise a tubular member that is insertable into a body lumen in a small diameter configuration and which can be expanded within the body lumen to an expanded mode. At least one of the ends of the tubular member will have a terminal edge that is disposed at least partially at an oblique angle relative to the lumen of the tubular member. The Fogarty patent suggests that the oblique end(s) of the tubular member provide a decreased risk of luminal occlusion attributable to hyperplasia in relation to other designs that do not include the oblique end(s). As the Fogarty patent states:

> The present intraluminal prostheses provide significant advantages over previously proposed designs, particularly for vascular uses. Any hyperplasia which occurs at the oblique ends of the present invention will occupy an oblique region of the lumen in which the present prosthesis is positioned. Although the total volume of hyperplasia may be the same or greater, the resulting occlusion is reduced, (i.e. effective residual lumen area is increased) because the hyperplasia is distributed axially over the surface of the lumen. In contrast, conventional prostheses having terminal edges perpendicular to the lumen axis will cause a greater dcegree of occlusion since the opposed regions of hyperplasia are axially aligned across a perpendicular cross section of the lumen. Thus the stenoses of the present intraluminal prostheses are effectively reduced over previous intraluminal prostheses designs.

(Fogarty patent, Col. 3, lines 5-20).

10. The Fogarty patent describes stents having several forms of construction, including a simple tubular member having a perforated tubular frame (column 4, lines 54-64), a member made up of a plurality of independent or interconnected structural elements (column 4, line 65 to column 5, line 3), a concentrically coiled sheet of biocompatible material (column 5, lines 4-13), a tube comprised of helically or spirally wound elements (column 5, lines 14-24), and a tubular member formed as inner and outer resilient tubular layers that are joined together at a proximal end and a distal end to define an annular cross-section that is fluid filled and held in place by a plastic material (column 5, lines 25-35). Regardless of the form of construction, the stent is provided with an oblique end to reduce the amount of luminal occlusion attributable to hyperplasia.

11. It is important to note that the Fogarty patent describes stents that have a balance of radial rigidity and axial flexibility that is obtained by selection of the form of construction (column 4, line 54 to column 5, line 35), the size and dimensions (column 6, lines 7-16), and the materials and material properties used to make the stent (column 6, line 17 to column 7, line 15). A reference is also included in the Fogarty patent to a stent that is formed of radially compressible band members in which flexibility is enhanced by providing only a limited number (two) of bridge elements. (Column 9, lines 1-10). Each of these features may be varied for a given stent construction described in the Fogarty patent to obtain a desired balance of radial rigidity and axial flexibility while at the same time not significantly increasing the incidence of luminal occlusion due to hyperplasia, which is the stated objective of the stent constructions described in the Fogarty patent.

12. In other words, to the extent that the Fogarty patent addresses the issue of radial rigidity of the stent, the patent states that the stent may be modified by changing its form of construction, its size and/or dimensions, or its material or material properties, all within the parameters described above and within the Fogarty patent. Nothing in the Fogarty patent suggests

that any other mechanism may be needed to provide a stent having a greater amount of axial rigidity than is obtainable from the stents described in the Fogarty patent.

13. The Khosravi patent describes a stent that includes a flat sheet having a mesh pattern formed on it. The stent assumes a cylindrical or spiral shape when the sheet is rolled up into both a reduced diameter form and an expanded diameter form. One end of the flat sheet has a buckle portion that includes rows of teeth such that, when the other end of the flat sheet is passed through the buckle, the rows of teeth engage the apertures in the mesh pattern to thereby "lock" the stent in an enlarged diameter condition. (Column 3, lines 5-22). In other embodiments, the flat sheet includes a plurality of projections formed on one edge such that, when the sheet is wound into an elongated cylinder, the projections engage the material along a helical seam (column 4, lines 30-42; column 5, lines 35-50) or a longitudinal seam (column 4, line 43 through column 5, line 34) to maintain the stent in an enlarged diameter form. In other embodiments, rows of teeth are formed on both ends of the flat sheet. (Column 5, lines 51-58). In still other embodiments, tabs are formed on one of the flat sheet and are adapted to engage teeth that are formed in elongated slots in the sheet. (Column 8, lines 7-13; column 8, line 65 to column 9, line 2). Other variations are also described.

13. It is important to note that each of the locking mechanisms for the stent structures described in the Khosravi patent includes protrusions that would tend to increase the incidence of luminal occlusions due to hyperplasia. This fact was even recognized in the Khosravi patent, in which the following is stated:

> In all of the stent embodiments disclosed, it is desirable to minimize the protrusions that line the inner surface of the stent, to minimize the possibility of fibrin accumulation and thrombosis. To this end, the inner surface of the stent (the outermost edge) may have fewer rows of protrusions along the longitudinal edge, to maintain a smooth interior by minimizing the protrusions exposed inside the stent, that is, to minimize the number of protrusions that are not engaged.

(Column 10, lines 47-55).

14. Based on these statements and the structure of the stents and locking mechanisms described in the Khosravi patent, and given the fact that a stated primary objective of the stent structures described in the Fogarty patent is to minimize hyperplasia caused by the interaction of the stent with the interior wall of the vessel, one of ordinary skill in the art would not be motivated to modify the stents described in the Fogarty patent to include the locking mechanisms described in the Khosravi patent. The Fogarty patent stents do not require an additional locking mechanism in order to function in the manner intended, and the addition of such a locking mechanism would run counter to the objective of reducing the incidence of luminal occlusion due to hyperplasia. More importantly, the statements from the Khosravi patent quoted in paragraph 13 above would actually steer one of ordinary skill in the art away from such a modification.

14. The Gray patent describes a stent that "overcomes some perceived shortcomings of prior art stents by providing a stent with axial flexibility." (Column 1, lines 46-47). The stent is a tubular member that includes a plurality of longitudinally disposed bands, with each band defining a generally continuous wave along a line segment parallel to the longitudinal axis. (Column 1, lines 50-53). The stent is delivered in a non-expanded state, then is expanded after delivery either with a balloon catheter or by use of self-expanding materials.

15. The Gray patent states that some prior art stent designs have "at least one important disadvantage," namely, that protruding edges occur when the prior art stents are flexed around a curve raising the possibility of inadvertent retention of the stent on plaque deposited on arterial walls. This may cause the prior art stents to embolize or move out of position and further cause damage to the interior lining of healthy vessels. (Column 1, lines 30-40). In contrast, the stents

described in the Gray patent have axially flexible bands that are arranged along the longitudinal axis and that avoid this disadvantage.

16. It is important to note that the coiled sheet design and the locking mechanisms of the stents described in the Khosravi patent would create protruding edges and cause damage to the interior lining of healthy vessels in the same manner as the "prior art stents" described in the Gray patent. This result is described as an "important disadvantage" in the Gray patent – i.e., a result to be avoided.

17. In addition, a person of ordinary skill in the art in October of 1999 would have recognized that the coiled sheet constructions of the stents described in the Khosravi patent have considerably less axial flexibility in the non-expanded state when compared to the tubular stents described in the Gray patent.

18. Accordingly, one of ordinary skill in the art would not be motivated to modify the axially flexible tubular stent design described in the Gray patent to include any of the coiled sheet designs or the locking mechanisms described in the Khosravi patent. More importantly, the objectives stated in the Gray patent for the stent designs described in that patent would actually steer one of ordinary skill in the art away from such a modification.

19. I certify under penalty of perjury that the information submitted in this Declaration is my true and correct opinion.

Dated: 6/29/05

By: _____
Eric Leopold

Eric Leopold

1330 Katherine Avenue
Redwood City, CA 94062

Education

M.S., Metallurgical and Materials Engineering
San Jose State University, 1995

B.S., Biomedical Engineering
University of Iowa, 1988

Qualifications

Seventeen years experience in the medical device industry, including product research and development, process engineering, production management, and project management. In-depth product knowledge of endovascular and minimally invasive medical products in the cardiovascular, neurovascular, and peripheral arenas.

Professional Experience

NovoStent Corporation (2004 – Present)
Designer of novel stents and delivery systems, initially for treatment of Superficial Femoral Artery disease. Start-up company founded in September 2003 currently consisting of six full time employees.

VP of R&D (4/04 – Present)
Manage technical team of three, a quality manager, and various outside consultants. Establish company direction, initial project plan and schedule. Led team to successful completion of Series A round objectives and initial quality system implementation.

Micrus Corporation (2000 – 2004)
Designer and manufacturer of interventional neuroradiology devices and delivery systems. Start-up company founded in 1996.

VP of R&D (1/03 – 2/04)
Managed three Project Managers and provided direction to twelve-person R&D team. Determined company strategic direction as member of executive staff. Identified and created strategic alliances, including technology purchases and co-development efforts. Maintained and developed intellectual property. Established physician relationships during conferences, SAB meetings, physician visits to Micrus, animal studies, and within hospital catheter labs.

Director of R&D (12/00 - 1/03)
Managed engineering design efforts, product enhancements, transfer support, and interdepartmental needs for projects including intravascular coil line extensions, hemorrhagic stent, advanced coils, and accessories. Hired, trained, developed and supervised nine-member team.

AngioTrax Inc. (1998 - 2000)
Designer of devices for use in mechanical transmyocardial revascularization. Start-up company founded in

Director of R&D (2/00-12/00)
Managed engineering design efforts, transfer support, and interdepartmental needs for the surgical and percutaneous TMR devices. Developed and supervised eight-member team.

PTMR Project Manager (10/98 - 2/00)
Lead engineer and project manager for design and development of percutaneous device project.

Prograft Medical Inc. (1995 - 1998)
Designer and manufacturer of stent-grafts for treatment of ilio-femoral disease, thoracic aneurysms, and abdominal aortic aneurysms. Start-up company founded in 1993, **acquired by W. L. Gore & Associates**.

Production Manager (11/96 - 10/98)
Established and managed production department, materials receiving, and quality control.

Senior Engineer (7/95 - 11/96)
Development engineer on ilio-femoral stent-graft team.

Guidant Corporation (1991 - 1995)
Designer and manufacturer of angioplasty catheters and coronary stents for treatment of occlusive disease.

Engineer III (7/93 - 7/95)
Technical leader on new coronary catheter platform project.

Engineer II (7/91 - 7/93)
Engineer on the Streak .014, Streak .010, and Elipse .014 angioplasty catheter teams.

Baxter Healthcare Corporation, Clintec International Division (1988 - 1991)
Designer and manufacturer of IV sets, enteral and parenteral formulations, automated compounding equipment and disposable sets.

Development Engineer (9/88 – 7/91)
Engineer of disposable sets for automated compounding and parenteral formulation design.

Patents

"Composition and Method for Treating Patients with Hepatic Disease"
November 5, 1996, Patent number: 5,571,783

"Implant Deployment Apparatus"
March 5, 2002, Patent number: 6,352,561

"Stent-Graft Deployment Apparatus and Method"
March 5, 2002, Patent number: 6,352,553

"Apparatus for Percutaneously Performing Myocardial Revascularization Having Means for Sensing Tissue Parameters and Methods of Use"
August 15, 2000, Patent number: 6,102,926

"Apparatus for Percutaneously Performing Myocardial Revascularization Having Controlled Cutting Depth and Methods of Use"
December 26, 2000, Patent number: 6,165,188

"Apparatus and Methods for Intraoperatively Performing Surgery"
Patent pending

"Apparatus and Methods for Performing Percutaneous Myocardial Revascularization and Stimulating Angiogenesis using Autologous Materials"
Patent pending

"Reloadable Sheath for Catheter System for Deploying Vasoocclusive Devices"
Patent pending

"Intravascular Flow Modifier and Reinforcement Device with Connected Segments"
Patent pending

"Stretch Resistant Therapeutic Device"
Patent pending

Office Action Summary	Application No.	Applicant(s)	
	09/427,260	KHOSRAVI ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,55-57 and 59-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,55-57 and 59-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. '520 in view of Khosravi et al. (5441515). Fogarty is explained supra. However, Fogarty does not disclose a plurality of locking elements extending from the inner section to the outer to secure the stent in the enlarged condition. Khosravi et al. teach (Figs. 4,5) a coiled sheet stent with a plurality of locking elements **25** that extend from the inner section to the outer section and secure the stent in an expanded condition. Khosravi teaches that locking elements are used on coiled sheet stents to prevent failure of the device, such that it maintains patency, col. 1, lines 49-51. It would have been obvious to one of ordinary skill in the art to incorporate a plurality of locking elements in the coil sheet stent as taught by Khosravi et al. in the stent of Fogarty such that it remains in the enlarged condition and does not collapse in the patient.

Claim 55-57,59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (5895406) in view of Khosravi et al. '515. Gray et al. (Fig. 6) show a stent with wing-like shape formed of a pair of longitudinal elements with each having undulations. It can be seen that longitudinal adjacent cells are connected at the tips of wing-like elements. Gray et al. disclose the stent pattern provides good axial flexibility, col. 2, lines 27-34. Gray also discloses the stent can be formed from many different

methods, col. 4, line 62. However, Gray does not disclose the stent is formed of a coiled sheet or include locking elements or that a shape memory material can be used. Khosravi is explained supra. Khosravi also teaches that stents can be made of shape memory materials for flexibility, col. 1, lines 55-59,64,65. It would have been obvious to one of ordinary skill in the art to use a coiled sheet to form the stent and include locking elements as taught by Khosravi et al. in the stent of Gray such that it prevents collapse. It would also have been obvious to one of ordinary skill in the art to use shape memory material as taught by Khosravi with the stent of Gray such that it is more flexible when inserting in tortuous vessels.

Response to Arguments

Applicant's arguments filed 6/18/04 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the features of Khosravi can be said to improve the stent of Fogarty.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 703-306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 703-308-2111. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738
Primary Examiner
Brian E. Pellegrino

Brian E Pellegrino